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09/194,598	11/30/98	DELESALLE	L 065691/0145

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EXAMINER
KIMBALL, M

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/194,598

Applicant

Delesalle et al.

Examiner

Melissa Kimball

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-19 is/are pending in the application.
- 4a) Of the above, claim(s) 13, 14, and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Status of the application Claims 12-19 are pending. Claims 1-11 were canceled by the amendment filed April 9, 2001.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous rejections not reiterated herein have been withdrawn based upon Applicant's arguments and/or amendments.

This application should be examined for errors. For example, Latin names should appear underlined or in italics (see claim 17).

Election/Restriction

1. Newly submitted claims 13, 14 and 19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to mitochondria and rely upon organelle transformation and isolation methods and further to methods of probing mitochondrial nucleic acid not required of the claims of the previously elected claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13, 14 and 19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 USC § 112

2. Claims 12 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to recombinant plant genomes with nucleic acid of chicory and sunflower, cytoplasm and plant cells comprising them, and to a methods of making plants comprising the recombinant genome. The claimed recombinant plant genome comprises nucleotide sequence conferring male sterility borne by sunflower orf 522 sequence or one of at least 50% homology to this sequence. The specification teaches two recombinant chicory genomes, *in planta*, expressing two types of cytoplasmic male sterility originating from sunflower. The specification does not describe the product encoded by the orf 522 nucleic acid sequence or the mechanism of its involvement in the fertility alteration of plants. The specification fails to teach characteristics to look for in a donor genome for successful expression of the male sterile phenotype that would be valuable in the claimed methods. There is no known or disclosed correlation between the recombinant plant genomes claimed which would unite this genus of genomes by any physical or chemical properties facilitating expression of cytoplasmic male sterility from sunflower. Therefore the large class of plant recombinant genomes encompassed in the instant methods and products are not described as though applicant had possession at time of

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filing. See for example *University of California v. Eli Lilly*, 119 F. 3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

3. Claims 12 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification teaches creating cytoplasmic male sterile (CMS) chicory plants, one which fails to release pollen (CT 52/3) and another which does not produce anthers (CT 41/1) (page 7, line 1-5) by protoplast fusion between sunflower and chicory (Example 1, beginning on page 5). It is known in the art that other methods can be used to create plant genomes conferring altered fertility, such as conventional backcross breeding methods, induced mutation breeding, and transgenic introduction of a exogenous sterility gene and that these methods are not always reliable or reproducible (Ar aya et al., col. 1-2). Each of these methods have requirements and considerations that are not taught or supported by the instant specification. The specification fails to teach the biochemical mechanism which results in the exemplified male sterility nor does it teach the interaction of this gene product in the genome of any other plant species. The methods of claim 18 are further unsupported because they read on reproducing the chicory plants. There is no demonstration of the heritability of either form of CMS obtained by the instant protoplast fusion methods. Furthermore, no restorer line is taught for continued breeding of the plants.



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which is embraced in the scope of claim 18. No fertility restoration gene has been identified, isolated or sequenced for use in a transformation or traditional breeding methods nor does the specification teach how to manage the genetic instability caused by mutation breeding. Yan teaches that the genetic match for the three breeding lines needed for reproduction of CMS plants, i.e. the male sterile, restorer, and maintainer line, are not easily found (col. 7, line 44-48) and that high ploidy levels further complicate the inheritance and stability of CMS breeding systems (col. 8, line 15-20). Given the unpredictability of CMS expression in plants, the number of ways sunflower infertility genes could conceivably be introduced to plants, the lack of guidance in the specification and the breadth of the claims to encompass the plant genome of any species, it would have required undue experimentation for one of skill in the art to make or use the claimed recombinant plant genomes.

Claim Rejections - 35 USC § 102

4. Claims 12 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rambaud et al. (1994).

Claims are drawn to a recombinant plant genome, cytoplasm or cell comprising chicory genes and the sunflower orf 522 sequence.

Rambaud et al. teach protoplast fusion of chicory (*Cichorium intybus*) and CMS sunflower (*Helianthus annuus*) to produce male sterile cybrids, as discussed previously. They teach that the cytoplasmic male sterile plants recovered from protoplast fusion comprised

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recombinant genomes which were made up of both chicory and sunflower genetic material and that the orf 522 DNA fragment from sunflower, known to produce cytoplasmic male sterility in sunflower, was present in the genome of the CMS cybrid. Rambaud et al. used protoplasts from *Cichorium intybus* in their fusion methods and therefore the recovered cells would comprise chicory nuclei.

Applicants argue in response to the previously rejected claims that Rambaud et al. have preliminary results which do not demonstrate that the orf 522 of sunflower definitively conferred male sterility to the chicory cybrids (response filed April 9, 2001). They argue that a non-enabling reference cannot anticipate the instant invention. Applicant's arguments filed April 9, 2001 have been fully considered but they are not persuasive. The claimed products, a recombinant plant genome with at least one chicory gene and the orf 522 sequence of sunflower, cytoplasm and cells comprising it, were produced by protoplast fusion by Rambaud et al. prior to the filing of the instant application.

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Claim Rejections - 35 USC § 103

5. Claims 12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rambaud et al. (1994) in view of Rambaud et al. (1993) and Laver et al. (1991).

Claims are drawn to recombinant genome, cytoplasm and cells comprising chicory and sunflower genetic material and further drawn to a method of producing a plant in the chicory genus by integrating the CMS-conferring nucleotides of the orf 522 sequence of sunflower.

Rambaud et al. (1994) teach protoplast fusion of chicory (*Cichorium intybus*) and CMS sunflower (*Helianthus annuus*) to produce male sterile cybrids, as discussed previously.

Rambaud et al. (1994) do not teach the sequence of orf 522.

Rambaud et al. (1993) teach fusing chicory and sunflower protoplasts to obtain CMS cybrid plants, as discussed previously. They teach using specific sequences to probe against the DNA of the parents and cybrids to detect genetic differences among them. Rambaud et al. teach the male sterile sunflower/chicory cybrids with a chicory phenotype designated CT41/1 and CT52/3 which have different forms of cytoplasmic male sterility expression from one another and they teach that seeds were generated from CT41/1 (page 348, col. 2).

Laver et al. teach differences in DNA of sterile and fertile sunflower and that the open reading frame (ORF) c which is 522 base pairs long is unique to sterile sunflower plants, as discussed previously. Laver et al. teach the sequence of the 522 bp ORF which matches the

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instant sequence 100%. They teach that male sterility is exploited for F1 seed production (page 185, col. 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to produce recombinant chicory plants by fusion with male sterile sunflower to introduce CMS, as taught by Rambaud et al. (1994) and to probe for sequences which are unique to the sterile genome, as taught by each of Rambaud et al. (1993) and Laver et al., to identify and select male sterile cybrids. A skilled artisan would recognize that fragments of the sequence taught by Laver et al. would be useful to select the cybrids which comprise the 522 bp open reading frame associated with sterility in the plants taught by Rambaud et al. (1994) because Laver et al. demonstrated the successful recovery of sterile sunflower plants using this method.

Applicants arguments, as applied to the new claims, state that there is no certainty taught by Rambaud et al. that orf 522 imparts CMS in chicory and that one of ordinary skill in the art would not be motivated to turn to the secondary references. Applicant's arguments filed April 9, 2001 have been fully considered but they are not persuasive. The teaching of Rambaud et al. (1994) to fuse chicory and sunflower for the express purpose of obtaining male sterile cybrids would be obvious to a plant scientist of ordinary skill because of the success in linking sterility effects of the orf 522 sequence taught by Laver et al. in sunflower. One would be motivated to produce such cybrids due to the general usefulness of male sterile plants for hybrid seed production, taught by Laver et al.

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GENERAL INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Kimball whose telephone number is (703) 305-6999. The examiner can normally be reached on weekdays from 9:30 am to 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

MLK

June 15, 2001


GARY BENZION
PRIMARY EXAMINER